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| APPLICATION NO.                  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------|-------------|----------------------|---------------------|------------------|
| 10/531,382                       | 04/15/2005  | Takehiko Sawabe      | 2007_0588           | 6520             |
| 513                              | 7590        | 04/21/2008           | EXAMINER            |                  |
| WENDEROTH, LIND & PONACK, L.L.P. |             |                      | ZUCKER, PAUL A      |                  |
| 2033 K STREET N. W.              |             |                      |                     |                  |
| SUITE 800                        |             |                      | ART UNIT            | PAPER NUMBER     |
| WASHINGTON, DC 20006-1021        |             |                      | 1621                |                  |
|                                  |             |                      |                     |                  |
|                                  |             |                      | MAIL DATE           | DELIVERY MODE    |
|                                  |             |                      | 04/21/2008          | PAPER            |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/531,382             | SAWABE ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Paul A. Zucker         | 1621                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 07 April 2008.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-23 is/are pending in the application.  
 4a) Of the above claim(s) 3,4 and 9-23 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1,2 and 5-7 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) 1-23 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/15/05, 6/24/05</u> .  | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group I, claims 1-7, and further election substitution pattern 2(a) in the reply filed on 7 April 2008 is acknowledged. Claims 1, 2 and 5-7 are readable thereon. Compounds having substitution patterns as set forth in 2(b)-2(n), as well as claims readable exclusively thereon, are held withdrawn from consideration as being drawn to a nonelected invention. Claims 3, 4 and 9-23 are held withdrawn from consideration as being drawn to a nonelected invention.

### ***Specification***

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1,2 and 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the limitation "easily removable" in line 4. No definition of the relative term "easily" is provided by Applicants and it is therefore impossible to determine the level of energy or effort which cannot be exceeded in the hydrolysis process in order for a group R to be

excluded from the compounds of formula (1). Claim 1 and its dependents are therefor rendered indefinite.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by TOSOH (JP 08-325526 12-1996, Machine translation). TOSOH discloses (Machine translation, paragraph [0015]) the compounds 2-acryloyloxyethylmalonic acid and 2-methacryloyloxyethylmalonic acid which correspond to the compounds of 2(j).
5. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Liebich et al (Journal of Chromatography B: Biomedical Sciences and Applications, Urinary Organic Acid Screening by Solid-phase Microextraction of the Methyl Esters, 1998, 713(2), pages 427-432). Liebich discloses (Page 431, column 1, Table 1, entry 4) the compounds ethyl malonic acid which the examiner presumes is easily hydrolyzed to malonic acid *in vivo*. Liebich therefore anticipates claim 1.

***Claim Objections***

6. Claims 1, 2 and 5-7 are objected to because they contain non-elected subject matter. Applicants should amend claims so they contain only elected compounds

having R equal to a C<sub>1-6</sub> alkylcarbonyloxy C<sub>1-6</sub> alkyl group. Appropriate correction is required.

***Conclusion***

7. Claims 1-23 are pending. Claims 1, 2 and 5-7 are rejected. Claims 1, 2 and 5-7 are objected to. Claims 3, 4 and 9-23 are held withdrawn from consideration as being drawn to a nonelected invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 571-272-0650. The examiner can normally be reached on Monday-Friday 5:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Evonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Paul A. Zucker/  
Primary Examiner,  
Art Unit 1621